

4218 '99 MAY 19 P3:22  
Dockets Management Branch (HFA-305)  
Docket No. 98N-1265  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD. 20857

I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Pamela S. Orth  
Signature

5-12-99  
Date

COMMENTS: \_\_\_\_\_

I am very, very concerned regarding continuing to obtain my compounded medication. I live in a very rural area with no compound pharmacy that can provide what I need near by and in fact many states away. I need to continue to obtain my compounded prescription for relief of my symptoms and for the quality of life I am enjoying now. I cannot take the commercial variety of hormones provided by Wyeth-Ayerst, namely PREMARIN. This is foreign to women's bodies and I am deeply sorry for the horses who have to endure a terrible life to produce it. Smaller companies devoted to women's needs are so VERY important and necessary and should not be restricted in any way. Don't take away our freedom of choice. My mother took the "popular" brand of estrogen and developed cancer. Unfortunately, I have her same symptoms that she took the estrogen for in the first place and I MUST HAVE the compounded prescription to alleviate these and for my health in general.

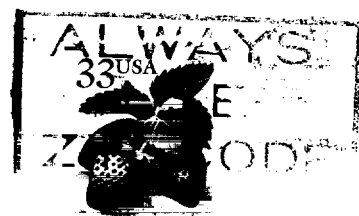
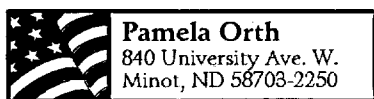
My doctor supports the compounded pharmacy, has prescribed the compounded medication and respects my need for something NOT AVAILABLE from other sources.

I totally object to the idea that only a limited number of prescriptions could be shipped out of state - how would one choose which women would get what they need? So the definition of an inordinate amount is absurd. It would be disastrous not to let women get the specialized medications needed.

C2357

98N-1265

Pamela S. Orth



4513 00 MAY 10 63:51

**DOCKETS MANAGEMENT BRANCH (HFA-305)**  
**DOCKET NO. 98N-1265**  
**FOOD AND DRUG ADMINISTRATION**  
**5600 FISHERS PARKWAY**  
**ROCKVILLE**

00000000 00000000